UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ACHIM BERTHOLD

Appeal 2007-0740
Application 09/830,300
Technology Center 1600

ON BRIEF

Before SCHEINER, ADAMS, and LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant appeals from a final rejection of claims 33-43 under 35 U.S.C. § 112, first paragraph, and claims 33-43 under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF CASE

The claims in this appeal are directed to an "active substance therapeutic system for application on the skin." The system, which comprises three polymer-containing layers, is utilized for transdermal

delivery of drugs. Specification 2: 1-11. It is also referred to as a drug "patch." *Id.* at 2: 6-8. The patch can be attached to the skin to achieve either local or systemic drug (a "therapeutically active substance") delivery. *Id.*

According to the specification, prior art multi-layered drug patches "tend to show cold flow" during storage, a property of a material in which the material "flows" during storage. *Id.* at 5: 17-22. This results in the patch becoming agglutinated, affecting its adhesive properties. *Id.* at 5: 21 to 6: 5.

According to the specification, an object of the invention is to "achieve a clear reduction" in cold flow. *Id.* at 8: 12-15.

> This object is achieved with an active substance-containing therapeutic system for application on the skin comprising at least two polymer-containing layers, by a layered structure of the [therapeutic system].
>
> The various layers differ in their glass transition temperature (Tg). The layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system. As a consequence, cold flow is reduced.

Id. at 8: 21 to 9: 6.

Glass transition temperature is the "temperature at which a polymer changes from the solid glassy state to the rubber-elastic state." *Id.* at 4: 8-9.

Claims 33-43, all the pending claims, are on appeal. The claims stand or fall together. Br. 10. We select claim 34 as representative of the claims for the purpose of deciding this appeal. It reads as follows:

> 34. An active substance-containing therapeutic system for application on the skin, said system comprising three polymer-containing layers, wherein;
>
> a first layer comprises a polymer having a glass transition temperature (T_g1), a second layer comprises a polymer having a glass transition temperature (T_g2), and a third layer comprises a polymer having a glass transition temperature (T_g3), said first, second and third layers being laminated on top of each other such that said second layer is located between said first layer and said third layer and is directly connected to the first layer and to the third layer; and
>
> wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different, wherein at least one of said three polymer layers contains at least one therapeutically active substance and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

The claimed system comprises three polymer-containing layers: 1) a first layer comprising a polymer having a glass transition temperature of Tg1; 2) a second, middle layer ("directly connected to the first layer and to the third layer") comprising a polymer having a glass transition temperature of Tg2; and a third layer comprising a polymer having a glass transition temperature of Tg3. The glass transition temperature of the first and third layers are the same or different. Tg2 of the middle layer is greater than Tg1 and Tg3.

DISCUSSION

Written description under § 112, first paragraph

Claims 33-43 stand rejected under 35 U.S.C. § 112, first paragraph. Br. 9. The Examiner contends that claim 34, added by amendment on Nov. 14, 1999, fails to comply with the written description requirement of § 112, first paragraph, because it "contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) . . . had possession of the claimed invention." Answer 3.

First, the Examiner asserts that there is no description in the specification of a therapeutic system having first and third layers which have different glass transition temperatures (Tg). *Id.* Secondly, the Examiner asserts that the specification does not describe a system where the third layer's glass transition temperature (Tg3) is different from Tg1 and lower than the second layer's glass transition temperature (Tg2). *Id.*

Appellants contend that the specification provides support for both claimed features. Br. 17-18.

The issue is whether the specification reasonably conveys to the person skilled in the art that the inventor had possession, at the time the application was filed, of the claimed therapeutic system recited in later-filed claim 34.

> In order to determine whether a prior application meets the "written description" requirement with respect to later-filed claims, the prior application need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the earlier date the applicant had invented what is now claimed. . . .

> The test is whether the disclosure of the application relied upon reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985).

Eiselstein v. Frank, 52 F.3d 1035, 1038-39, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995).

Fig. 1 of the originally-filed specification shows a therapeutic system which consists of five layers. Specification 10: 10-18. Layers b), c), and d) contain polymers with glass transitions temperatures of Tg1, Tg2, Tg1, respectively. *Id.* at 10: 15-18. Tg2 is greater than (>) Tg1. *Id.* at 10:18. This configuration is an embodiment encompassed by the scope of claim 34. The Examiner confines the application's written description to this one example, asserting that the broader configuration recited in claim 34 is not described by the specification.

We do not agree. The specification requires the therapeutic system to comprise "at least two polymer-containing layers," where each layer has a different Tg. Specification 8: 21 to 9: 2. In other words, when two polymer-containing layers are present, they must each have a different Tg. We do not see any basis in the application for inferring from this restriction that *only* two different Tg polymers can be utilized in the system. To the contrary, the application broadly states that "[t]he various layers [comprising the therapeutic system] differ in their glass transition temperature (Tg)." *Id.* at 9: 1-2. *See* similar disclosures at 10: 1-5 and 13 (claim 1). In our view, the most reasonable reading of the application is that, in a system with more than two polymer-containing layers, the Tg can be different for each layer.

In a system with three polymer-containing layers, this would mean that each of the three layers could have a different polymer Tg, providing support for claim 34.

The next question is whether the specification describes a three-layered configuration in which the middle polymer-containing layer is sandwiched between top and bottom layers having *different* and *lower* Tgs. Fig. 1 shows the sandwich configuration in which the top and bottom layers have the *same* and *lower* Tg. However, the specification does not indicate that a particular Tg configuration is critical or limiting, stating only that cold flow is reduced by having "layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system." Specification 8: 21 to 9: 10. Fig. 1 is one three-layered configuration which achieves this goal. There are not a myriad of other configurations possible, but only a few. The arrangement where all three layers contain polymers with different Tgs, but in the same Tg configuration as Fig. 1 (middle layer having the higher Tg), is readily envisioned. We find this configuration is "necessarily" described in the specification when Fig. 1 is read in view of the disclosure that "the polymers used for the different layers differ in their glass transition temperature." Specification 13 (original claim 1). *See In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998).

For the foregoing reasons, we reverse the rejection of claims 33-43 as lacking written description.

Obviousness under § 103(a)

The Examiner relies on the following prior art:

Chien et al. (Chien)	U.S. Pat. 5,023,084	Jun. 11, 1991
Otsuka et al. (Otsuka)	U.S. Pat. 5,151,271	Sep. 29, 1992
Patnode et al. (Patnode)	U.S. Pat. 6,063,838	May 16, 2000

Claims 33-34 stand rejected as obvious under 35 U.S.C. § 103(a) over Otsuka, by itself, or in view of Patnode. Br. 9. Claims 33-34 stand rejected as obvious under 35 § U.S.C. 103(a) over Otsuka, by itself, or in view of Chien. *Id.*

Otsuka describes a composite pressure-sensitive "adhering multilayer medicinal preparation capable of increasing drug supply to the skin." Col. 1, ll. 13-16.

> [I]t comprises at least two layers, namely a layer of a macromolecular substance having pressure-sensitive adhesiveness at ordinary temperatures and a polymer layer adjacent to said macromolecular substance layer, that at least one of the macromolecular substance layer and polymer layer at least contains a percutaneously absorbable drug and the other at least contains an adjuvant capable of increasing percutaneous drug absorption, and that the drug and adjuvant respectively can migrate into the adjacent macromolecular substance layer and polymer layer.

Col. 2, ll. 5-15.

The polymer layer has "a glass transition point (Tg) of not lower than -50°C, preferably -45°C to +75°C, practically -40°C to +45°C." Col. 2, ll. 24-26. The macromolecular layer has "a Tg of -70°C to -10°C." Col. 3, ll. 11-12. Example 1 shows a composite having 1) a macromolecular layer

comprising a polymer with a Tg of -55°C and 2) a polymer layer having a Tg of -13°C. Col. 7, ll. 34-46.

The Examiner contends that it would have been obvious to one of ordinary skill in the art to have modified Otsuka's specifically exemplified two-layered patch by joining a second macromolecular layer to the other side of the polymer layer. The Examiner contends that the motivation to have incorporated an additional macromolecular layer into Otsuka's two-layered patch is provided by Otsuka in view of Patnode and/or Chien, the latter two which teach multi-layered transdermal patches. Answer 6, 9.

Appellant contends that there is no teaching or suggestion in the cited prior art of a therapeutic system recited in claim 34.

The issue is whether the Examiner provided adequate motivation under 35 U.S.C. §103(a) to have modified Otsuka's teachings by laminating a second macromolecular layer to the polymer layer, where the macromolecular layer has a Tg lower than the Tg of the polymer layer.

During patent examination, the Examiner bears the initial burden of presenting a prima facie case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). Prima facie obviousness requires that each element of the claimed invention be identified in the prior art and that "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead the individual to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). *See In re Huston*, 308 F.3d 1267, 1280, 64 USPQ2d 1801, 1810 (Fed. Cir.

2002). When a prima facie case is made, the burden shifts to the patent applicant to come forward with evidence and/or argument supporting patentability. *Oetiker,* 977 F.2d at 1445, 24 USPQ2d at 1444.

The Examiner's case is premised on reading Otsuka's disclosure to teach more than one macromolecular layer. Answer 14. Based on this reading, the Examiner argues that, when two macromolecular layers are present in Otsuka's medicinal preparation, "the only configuration that would work is sandwiching the polymer layer between the two macromolecular layers." *Id.* at 15. The Examiner contends that the skilled worker, following Otsuka's teaching of a composite comprising a polymer layer with Tg higher than the macromolecular layer (col. 7, ll. 34-46, Example 1), would choose the second macromolecular layer to have a Tg which is lower than the polymer layer's Tg, meeting the requirements of claim 34. *Id.* at 15-16.

The problem with the Examiner's argument is that the Otsuka does not clearly teach a second macromolecular layer. We agree with Appellant that Otsuka's disclosure at col. 1, ll. 13-16, is at best ambiguous, and certainly not a clear teaching of more than one macromolecular layer. There is no additional disclosure in Otsuka which supports the Examiner's interpretation. In Otsuka's examples, only a single polymer and single macromolecular layer are utilized. Col. 7-8. An additional layer is disclosed, but as a support for the polymer layer. Otsuka does not describe the Tg of the support layer nor state that it has the properties of a polymer or macromolecular layer. Col. 2, l. 63-col. 3, l. 2; Br. 12.

We also not persuaded that it would have been obvious to have produced a three-layered patch from Otsuka's teaching by laminating a second macromolecular layer to the other side of the polymer layer. Answer 15-16. As argued by Appellant, the macromolecular layer acts to "secure adhesion of the preparation to the skin," making it less likely that it would be included as a second, additional layer, which is placed on top of the polymer layer and away from the skin surface. Col. 3, ll. 3-6; Br. 21, 25.

Furthermore, the Tg of the macromolecular layer is described to result in a base composition which "has an increased shape-holding property, leaves no residue on the skin and causes no skin irritation at the time of peeling off." Col. 3, ll. 14-18; Br. 26-27. Since these properties relate to the skin adhering function, we agree with Appellant that it would not have been obvious to have picked these Tg properties for a layer not in contact with the skin in the sandwich-type configuration proposed by the Examiner. Br. 27.

The Examiner relies on Patnode and Chien for teaching additional and multiple (e.g., two or more) drug-containing layers in a therapeutic system for application to the skin. Neither of these references, however, provide any reason to have selected a third layer with a Tg that is less that the Tg of the second and middle layer as required by claim 34.

"Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight." *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Here, we see no clear reason – other than hindsight – to have picked a third layer laminated on top of a second layer in

a therapeutic system for application on the skin, where the Tg of the second layer is greater than the Tg of the third layer. Accordingly, we reverse the rejection of claim 33-43.

REVERSED

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